What Goes Wrong in Homecare?

Angela King, BS, RPFT, RRT-NPS

CONGRESS 2016

Conflict of Interest

I have affiliations with, special interests, or have conducted business with the following companies that in context with this presentation might possibly constitute a real or perceived conflict of interest:

Breas

Hamilton Medical

Ventec Life Systems

Owner: Mobile Medical Homecare

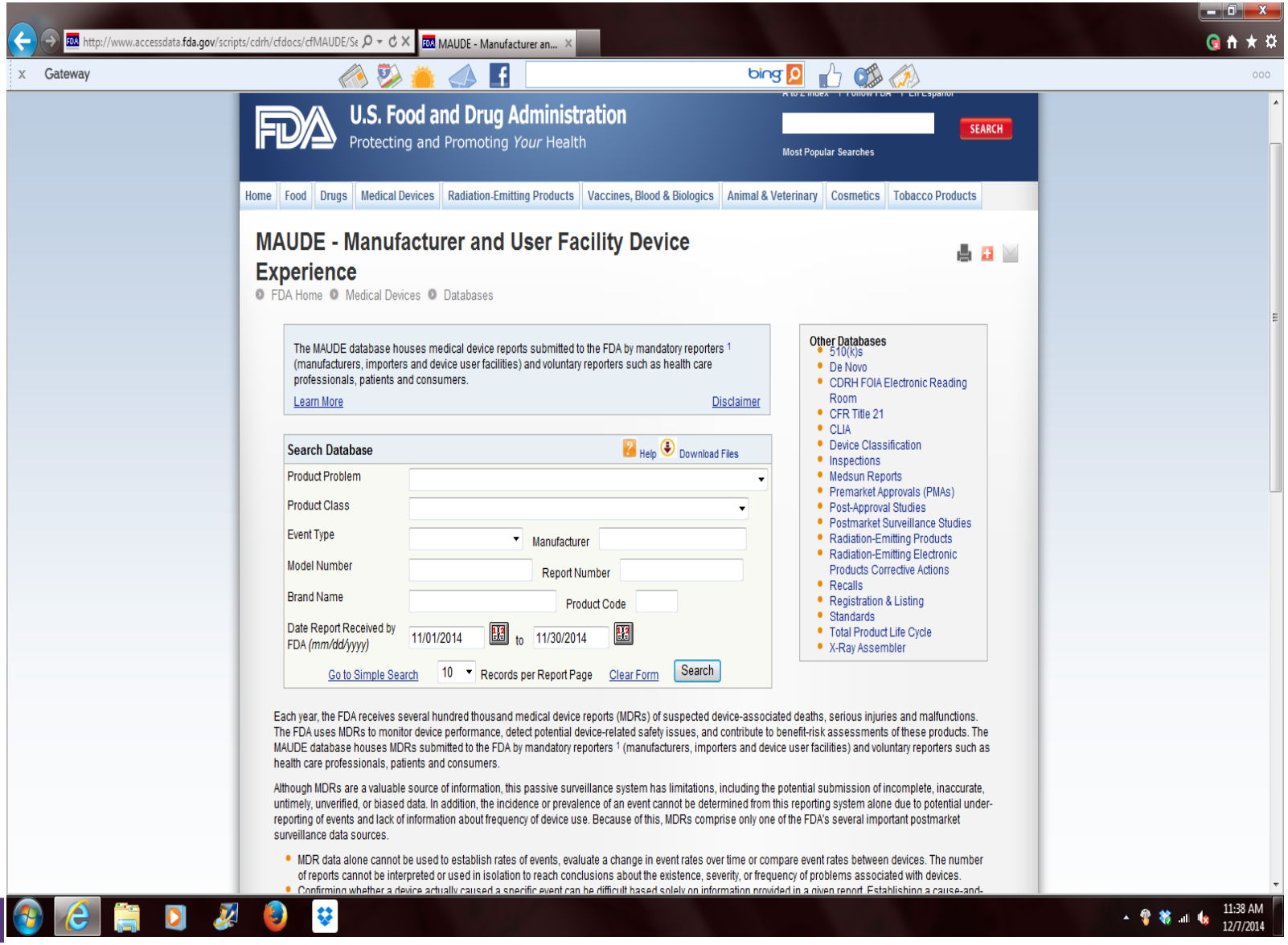
Husband Owns: Mobile Medical Maintenance & Repair

Objectives

Learning objectives for this presentation:

1. Participants will be able to list at least three common homecare safety issues.
2. Participants will be able to list at least three simple steps the RT can take to promote patient safety.

FDA MAUDE Database



National Fire Protection Association (NFPA)

National Fire Protection Association

The authority on fire, electrical, and building safety

- www.nfpa.org
- 617-770-3000
- Quincy, MA.

Oxygen Issues

MAUDE Database

- 1/1/2009 to 6/30/2016 = 130 Deaths related to oxygen concentrators
  - 58 deaths due to fire, 26 definitely attributed to smoking
  - 21 deaths due to low flow
  - 14 deaths due to low FiO2
  - 8 deaths due to unknown malfunction
  - 9 deaths due to power loss

NFPA Files

Nebraska

A disabled woman on oxygen and 2 firefighters were killed in a fire when a cigarette ignited a sofa. The oxygen system caused the fire to spread quickly to the rest of the house– which caused the roof to collapse while the firefighters were on it.

NFPA Files

Tennessee

Two elderly neighbors died in their apartment building when one of the women discarded a cigarette on a recliner. The fire was intensified by her oxygen tubing along the chair. The neighbor woman, who used a walker, died from smoke inhalation as she tried to leave the building.

NFPA Files

Oregon

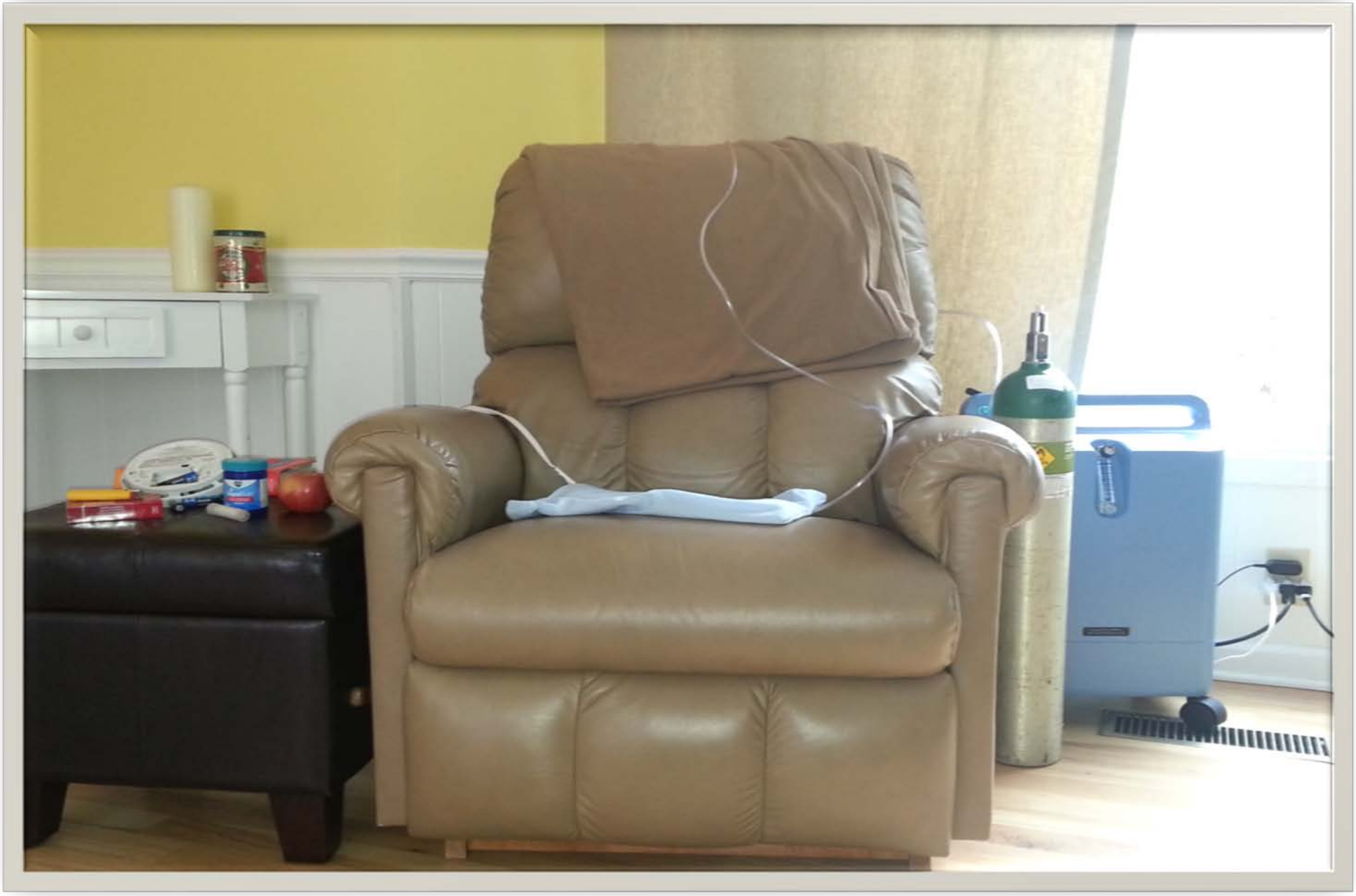
Fire started in group home in a recliner, then was intensified by stored oxygen in one of the resident's bedrooms. 4/5 residents had mobility impairments (walker, wheelchair). 4 residents perished in the fire.

NFPA Files

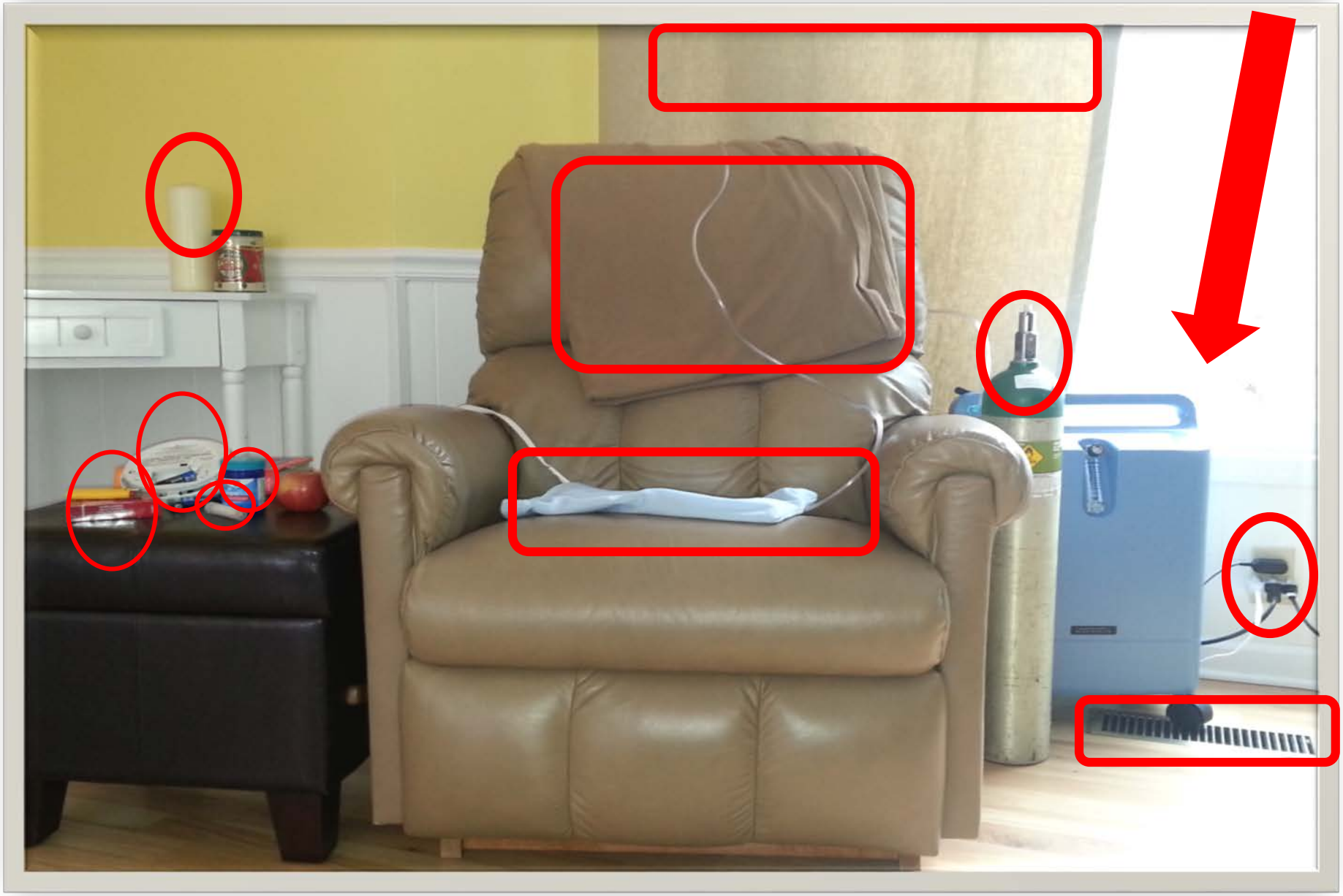
California

A 55 year old blind man died of exposure to heat and smoke when his bedroom caught fire. Several large-diameter power cords were plugged into power strip, which was covered by clothes and books. The overloaded strip eventually created enough heat to ignite. His concentrator and portable tanks contributed. The battery had been removed from his smoke detector.

How Many Safety Issues?



How Many Safety Issues?



CPAP (BZD) Issues

CONGRESS 2016

78 BZD Device Deaths

- 8 machine failures
  - 24 hour ALS pt. / corrosion
  - 1 needed “loaner”
  - 1 error code/large leak
- 1 valve stuck on FFM

- Device turned off, mask on
- 2 entangled in tubing
- 4 accidental disconnect
- 1 O2 disconnect, no alarm
- 4 vomit (2 d/t smell)
- 1 nose-bleed

RAD (MNS) Issues

CONGRESS 2016

A Fatal Complication of Noninvasive Ventilation

To the Editor: Noninvasive positive-pressure ventilation is widely used in patients with chronic respiratory failure due to neuromuscular diseases such as amyotrophic lateral sclerosis.[1] Noninvasive positive-pressure ventilation can be used intermittently, the equipment is portable, and ventilation does not interfere with eating and speaking. It is considered safe, and most problems that occur are related to the fit of the mask and the risk of aspiration pneumonitis.[2] We describe a complication we have not previously seen reported.

The patient was a previously healthy 53-year-old man with amyotrophic lateral sclerosis who was started on nocturnal noninvasive positive-pressure ventilation (inspiratory pressure, 10 cm of water; expiratory pressure, 2 cm of water). He tolerated this well and decided that he did not want invasive mechanical ventilation in the future. The patient's disease progressed, but he continued to work full-time and used noninvasive positive-pressure ventilation all night and most of the day. He obtained a second ventilator, which he kept at work.

More than a year after noninvasive ventilation was initiated, the patient's ventilating unit failed. The machine's error code indicated that there had been a power-supply failure. Respiratory distress quickly developed, and the patient was taken to a local hospital but died of respiratory failure before ventilation could be reinstituted.

This case demonstrates a problem that is likely to become more common as increasing numbers of patients with chronic respiratory failure use noninvasive positive-pressure ventilation. It is important to realize that technical failures of the machines in these cases can be catastrophic. Patients and their caregivers should be counseled that noninvasive positive-pressure ventilation is not a substitute for tracheostomy and mechanical ventilation. Patients need to be made aware of the consequences of ventilator failure. We recommend that our patients consider making the transition to tracheostomy if they require full-time ventilatory support. Although this event has not decreased our use of noninvasive positive-pressure ventilation, we have begun to teach caregivers how to provide bag-and-mask ventilation to patients in the event of an emergency. If the equipment is available, this simple technique may be lifesaving.

NOAH LECHTZIN, M.D., M.H.S.
CHARLES M. WEINER, M.D.
LORA CLAWSON, M.S.N., C.R.N.P.
Johns Hopkins University School of Medicine
Baltimore, MD 21287

MAUDE Report

In other words, if he died because the machine stopped, he shouldn't have been on that type of machine!!!

Using RADs for NMD

- Not all Bilevel devices have power loss alarms
- Most Bilevel devices do not have internal battery
- System problem (13 month capped rental)
- No reimbursement option for second Bilevel device
  - Provide bag/mask when appropriate
- Consider transitioning to ventilator with alarms & battery capability if device used > 12- 16 hours per day (regardless of NIV or IV)

Maude Database: MNS Deaths

In the past 6+ years:

3 deaths due to power failure

3 deaths from machine failure

1 death from patient disconnect

3 deaths from non-vented mask

1 death from tipped humidifier

Ventilator (CBK, NOU) Issues

Top 10 Health Technology Hazards for 2015

#1: Alarm Hazards: Inadequate alarm configuration policies and procedures

#5: Ventilator Disconnections not caught because of mis-set or missed alarms

health DEVICES

ECRI Institute
The Discipline of Science. The Integrity of Independence.

AARC CONGRESS 2016

MAUDE Report #2031702-2009-00220, Report Date 12/3/2009, LTV, Death

It was reported that the patient decannulated while connected to the ventilator. The patient's mother reported the ventilator did not alarm, and the patient passed away.

MAUDE Report #2031702-2011-00096, Report Date 5/3/11, LTV, Death

It was reported that the patient's mother came into the room and found the patient had pulled his trach out and had passed away. The patient's mother reported the ventilator had no audible alarms.

MAUDE Report #2518422-2013-01772, Report Date 8/2/2013, Trilogy, Death

The mfr received info indicating a patient expired while a ventilator was in use. The customer alleges the ventilator did not audibly alarm when the flex tube became disconnected from the patient's tracheostomy tube.

MAUDE Report # 3502341, Report Date 10/17/2013, Trilogy, Death

Mother stated patient was napping in a playpen and had decannulated himself. Patient was on one end of playpen and his trach tube at the other end still attached to the ventilator circuit. Mother stated that the SIMV rate was set at 12 and ventilator was not alarming. Mother stated that ventilator started to alarm once she disconnected the trach tube from the ventilator circuit. Mother was asked by DME personnel if the pulse oximeter was alarming and mother stated that the pulse oximeter had not been placed on the patient. Mother stated that doctor told her that the pulse oximeter could be used at night, so it was not on the patient.

MAUDE Report #2518422-2011-00113, Report Date 8-23-2011, Trilogy, Death

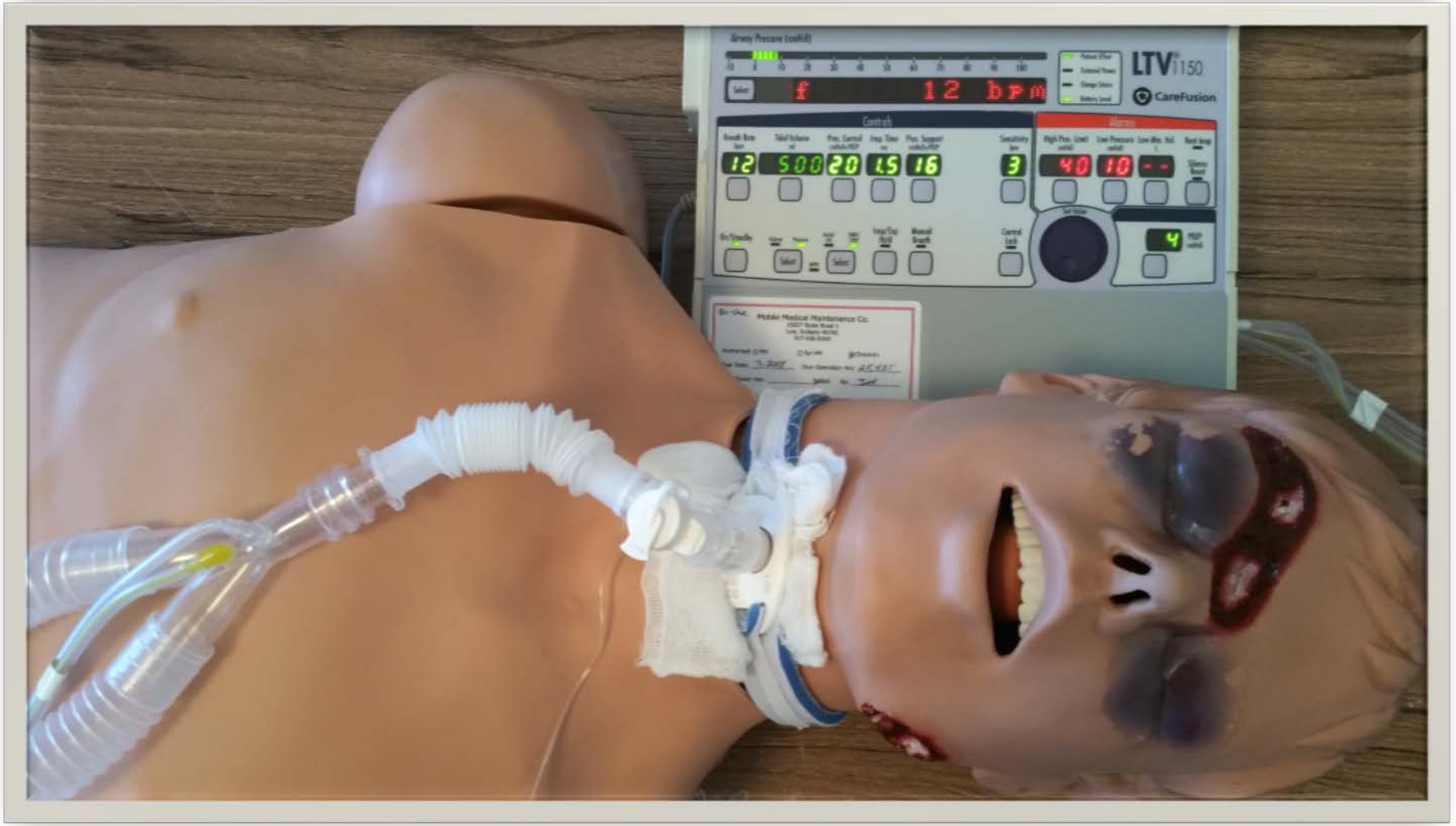
The mfr received info alleging a ventilator failed to audibly alarm when a pt pulled his tracheostomy tube out. The pt expired. According to the caregiver, the ventilator was not audibly alarming for the circuit disconnect when she entered the room. The ventilator was returned to the mfr for investigation. **The device passed all testing and was found to operate and audibly alarm as designed.** The ventilator's error log was reviewed and no errors which would indicate a device or alarm malfunction were present.

(continued) The direct view report confirmed the circuit pressure never dropped throughout the reported event. The pt circuit that was in use at the time of the event contained a heat moisture exchanger (hme) and a size 4.0 trach tube. At the time of the event, the pt circuit appears to have had enough resistance from the hme and small tracheostomy tube size to maintain enough pressure so that the set low pressure limit was not exceeded to result in an audible alarm.

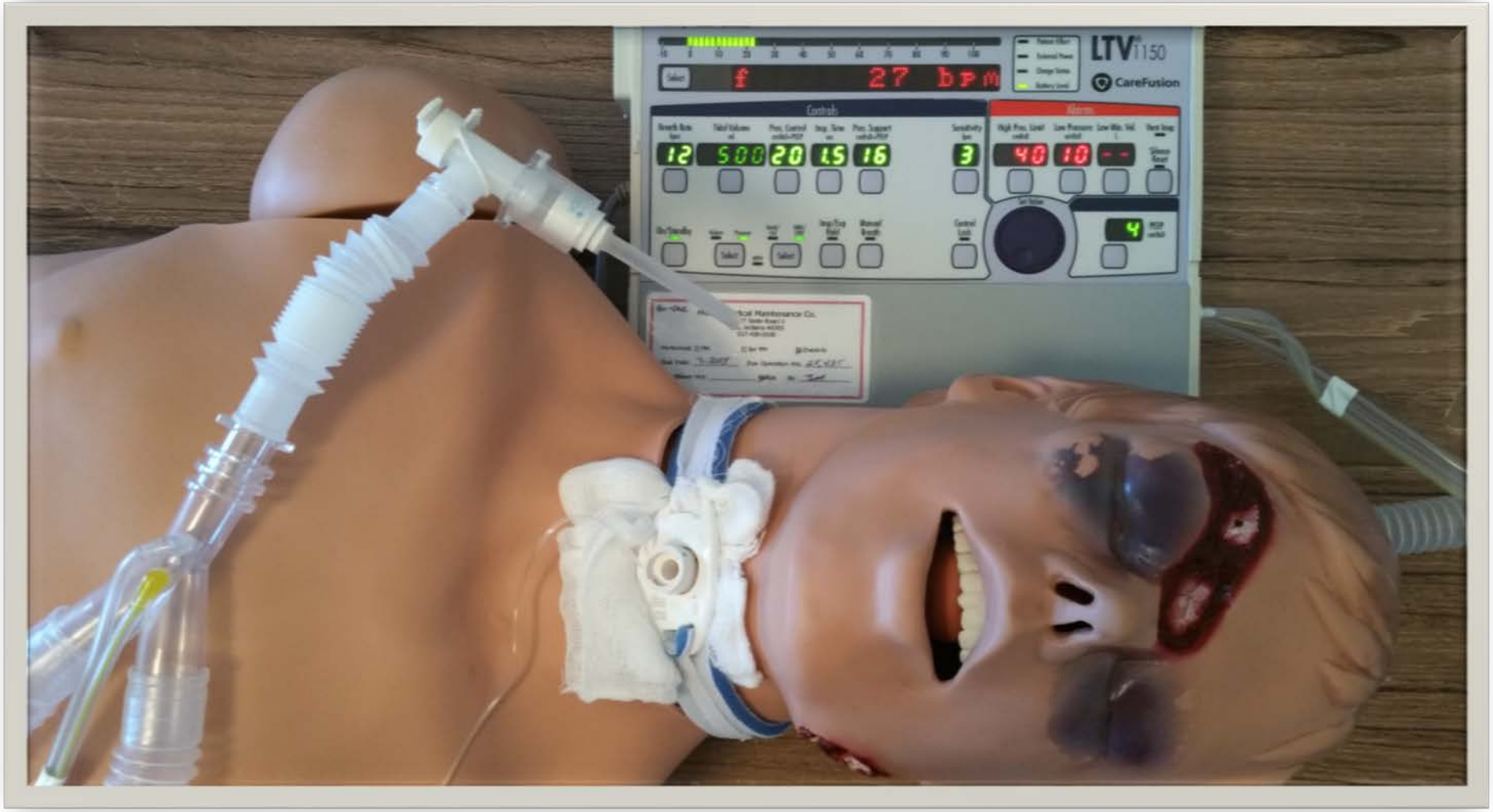
20 years, 39 Children, 8 Deaths				
No.	**Diagnosis**	**No. years on vent**	**Cause of death**	**No. years at home**
1	SCI C2 Quadriplegia	16 y	Ventilator disconnection, died at home	15 y, 7 m
2	SCI C2 Quadriplegia	5 y	Cause unknown, found dead in bed at home	3 y, 8 m
3	SCI C2 Quadriplegia	12 y, 10 m	Bowel obstruction, peritonitis, died in hospital	6 y, 8 m
4	SCI Quadriplegia	8 y, 6 m	Unknown, died sitting in wheelchair after eating	0 y, 5 m
5	SMA	5 y, 1 m	Seizures, metabolic, died in hospital	4 y, 8 m
6	Demyelinating neuropathy	4 y	Fall-accident in wheelchair, died while living at home	3 y, 1 m
7	Myotubular myopathy	5 y	Overwhelming viral illness, died in hospital	3 y, 0 m
8	Unknown myopathy	11 y, 10 m	Ventilator disconnection, died at home	10 y, 5 m

Adapted from: Gilgoff RL, Gilgoff IS. Long term follow up of home mechanical ventilation in young children with spinal cord injury and neuromuscular conditions. J Pediatrics 2003; 142: 476-480.

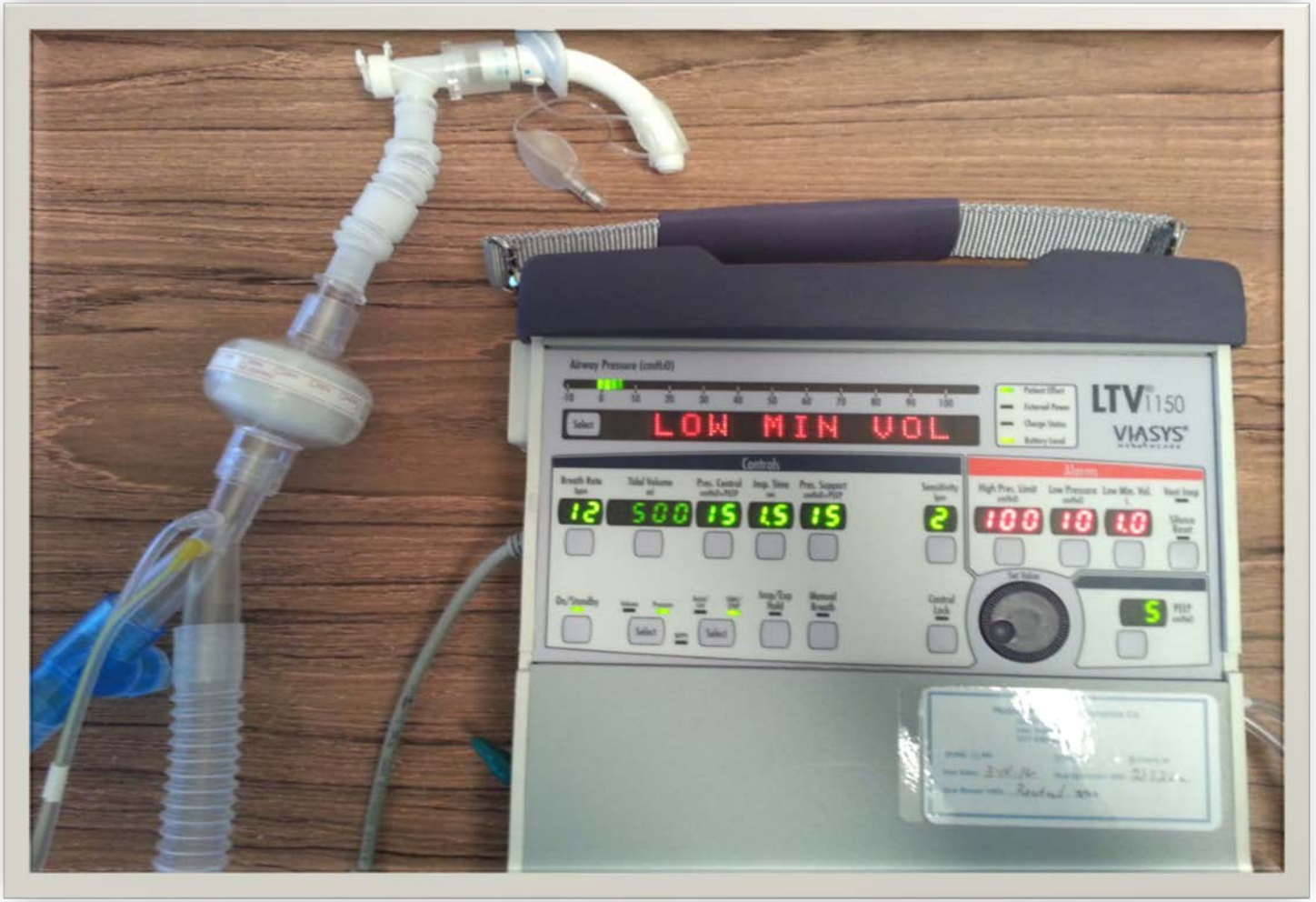
SIMV, PC 20, PS 16, PEEP 4, 12 bpm
HP 40, LP 10



SIMV, PC 20, PS 16, PEEP 4, 12 bpm
HP 40, LP 10



Test With Emergency Tube



No Alarm Conditions

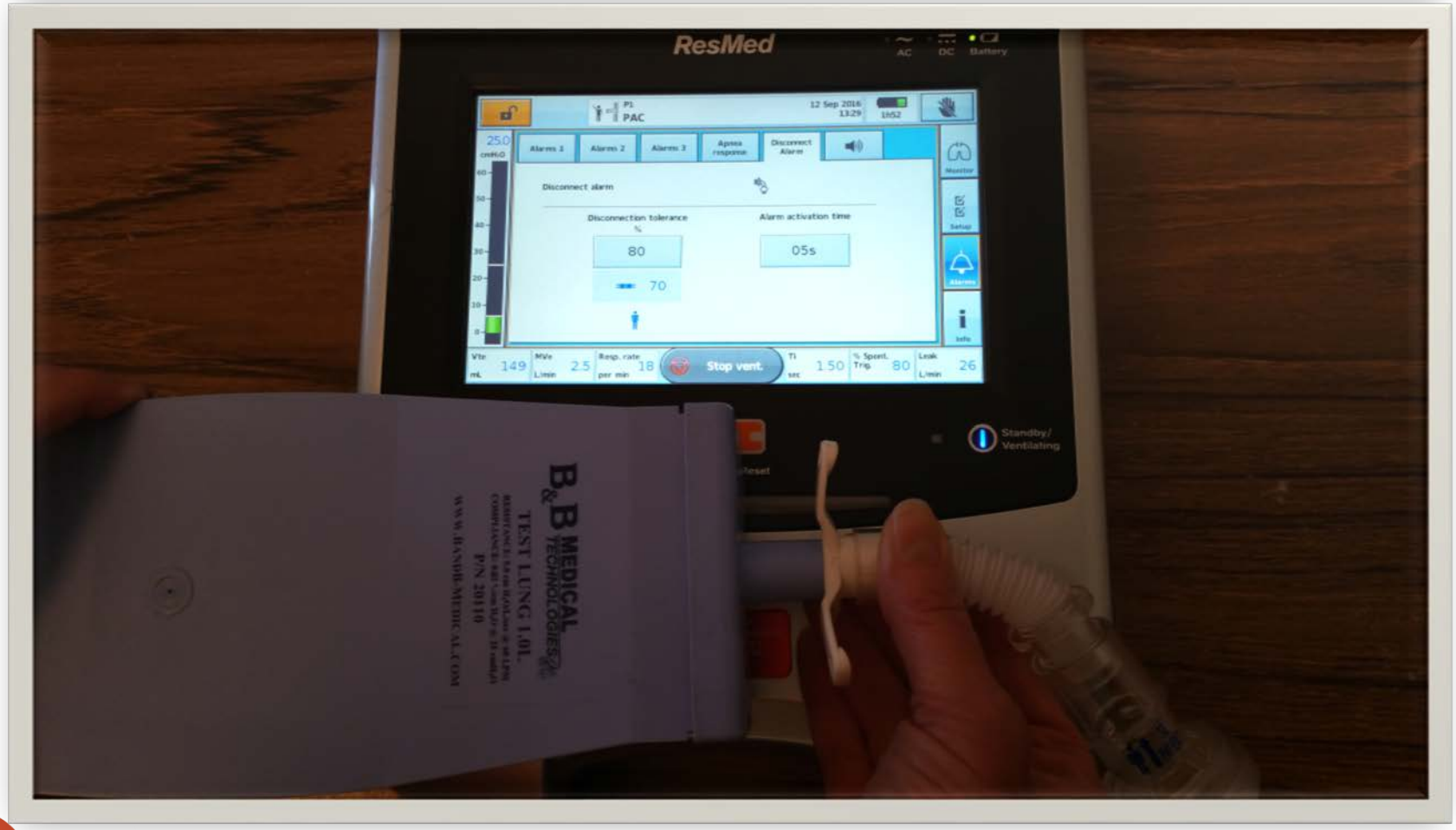
Chest. 2001 Feb;119(2):562-4.
Kun SS. Home ventilator low-pressure alarms fail to detect accidental decannulation with pediatric tracheostomy tubes.

CONCLUSION: We conclude that ventilator low inspiratory-pressure alarms fail to alarm during simulated decannulation with small tracheostomy tubes commonly used in children. We speculate that **low-inspiratory-pressure alarms set at 4 cm H_2O below the desired PIP** will detect more decannulation than when set at 10 cm H_2O below the desired PIP.

Astral Disconnection Tolerance Alarm

CONGRESS 2016

Astral Disconnection Tolerance Alarm



Astral Disconnection Tolerance Alarm – Simulated Decannulation

CONGRESS 2016

Astral Disconnection Tolerance Alarm - Disconnect at Catheter Mount

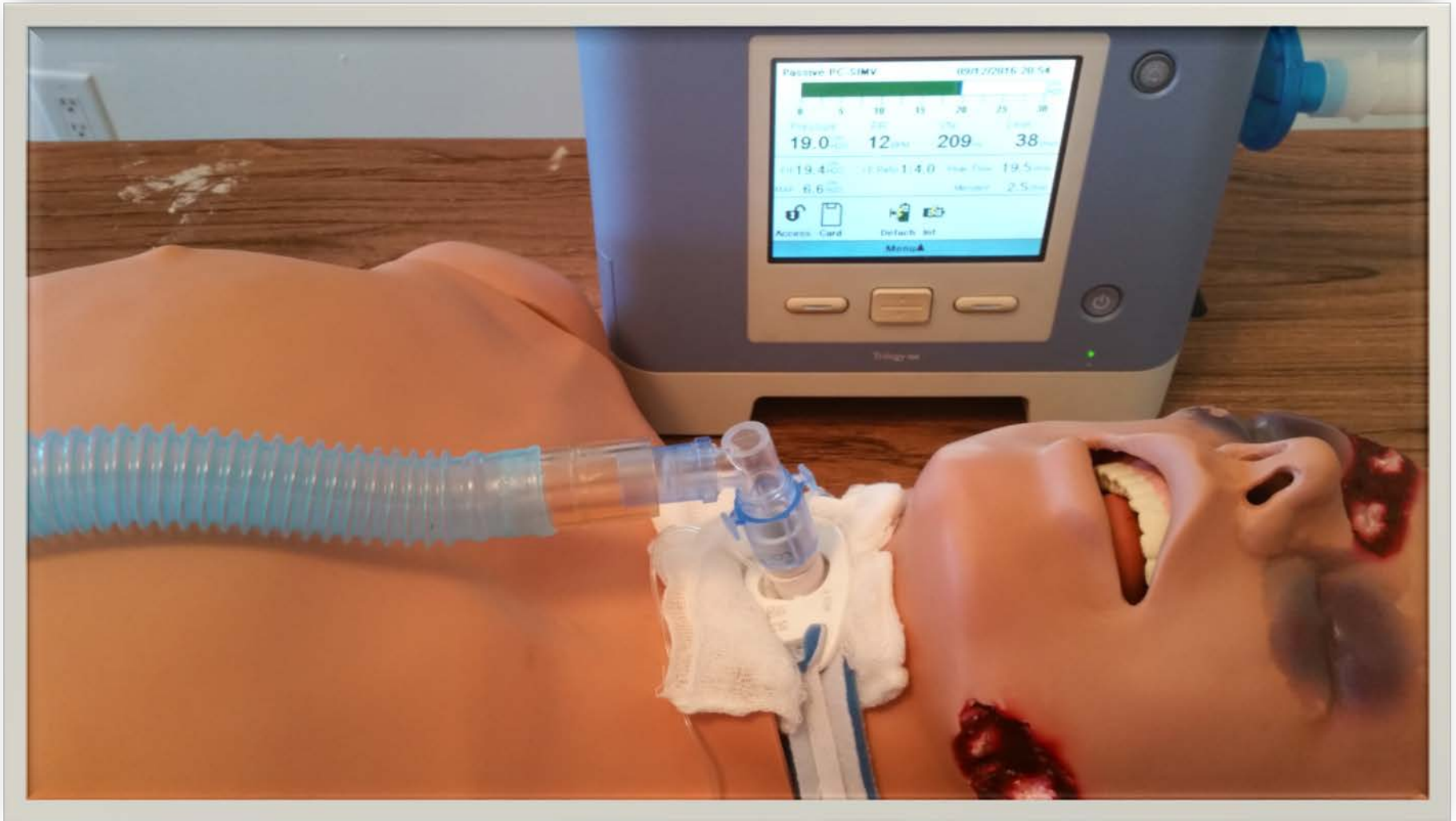
MAUDE Report #2031702-2012-00122 , Report Date 5/8/12, LTV

It was reported that the patient passed away while connected to the ventilator. The ventilator did not alarm. The patient was on a flex tube which was kinked.

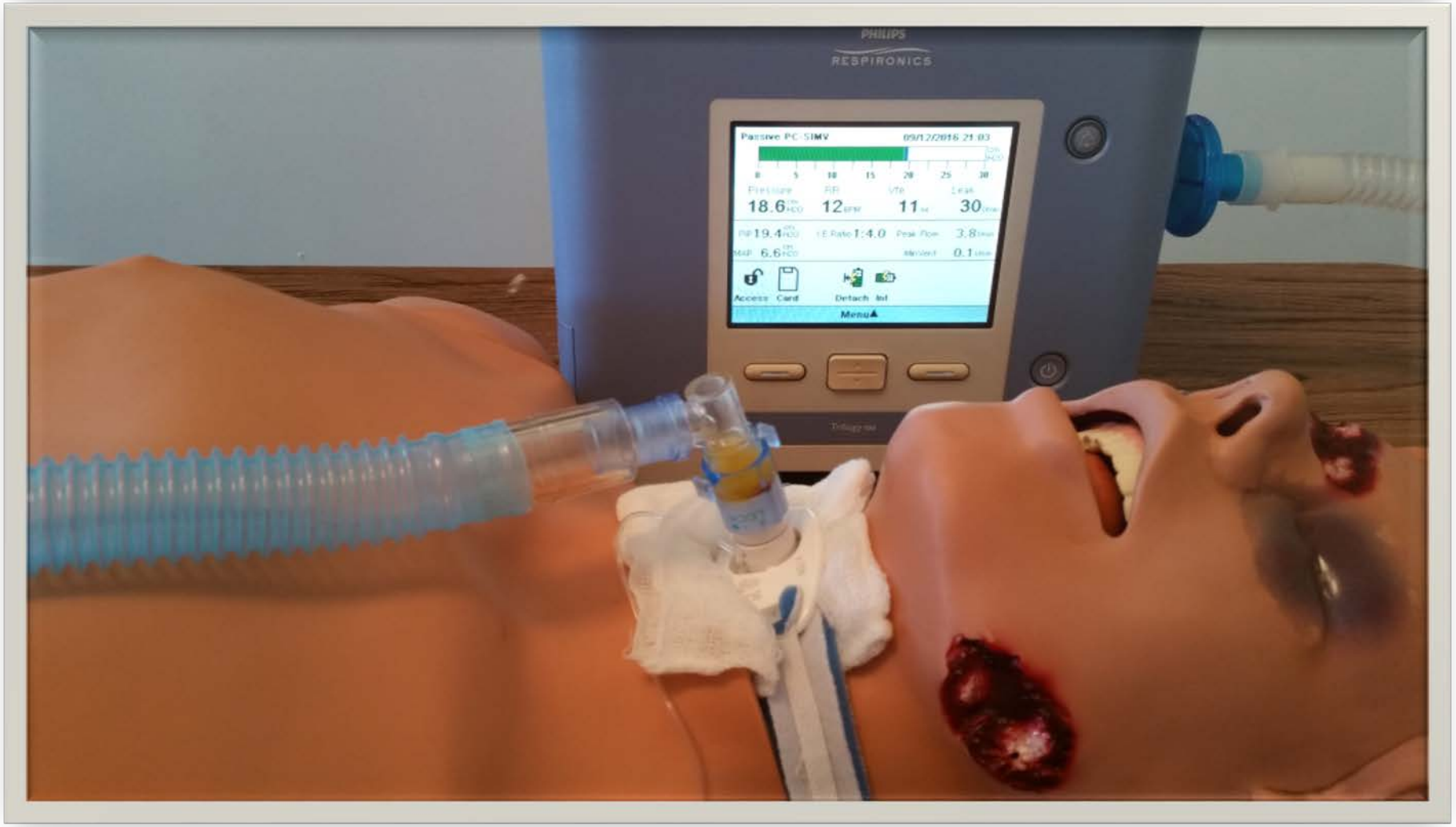
MAUDE Report #2031702-2010-00060 , Report Date 4/8/10, LTV

It was reported that the patient had a mucus plug while connected to the ventilator, but the ventilator did not alarm. The patient passed away.

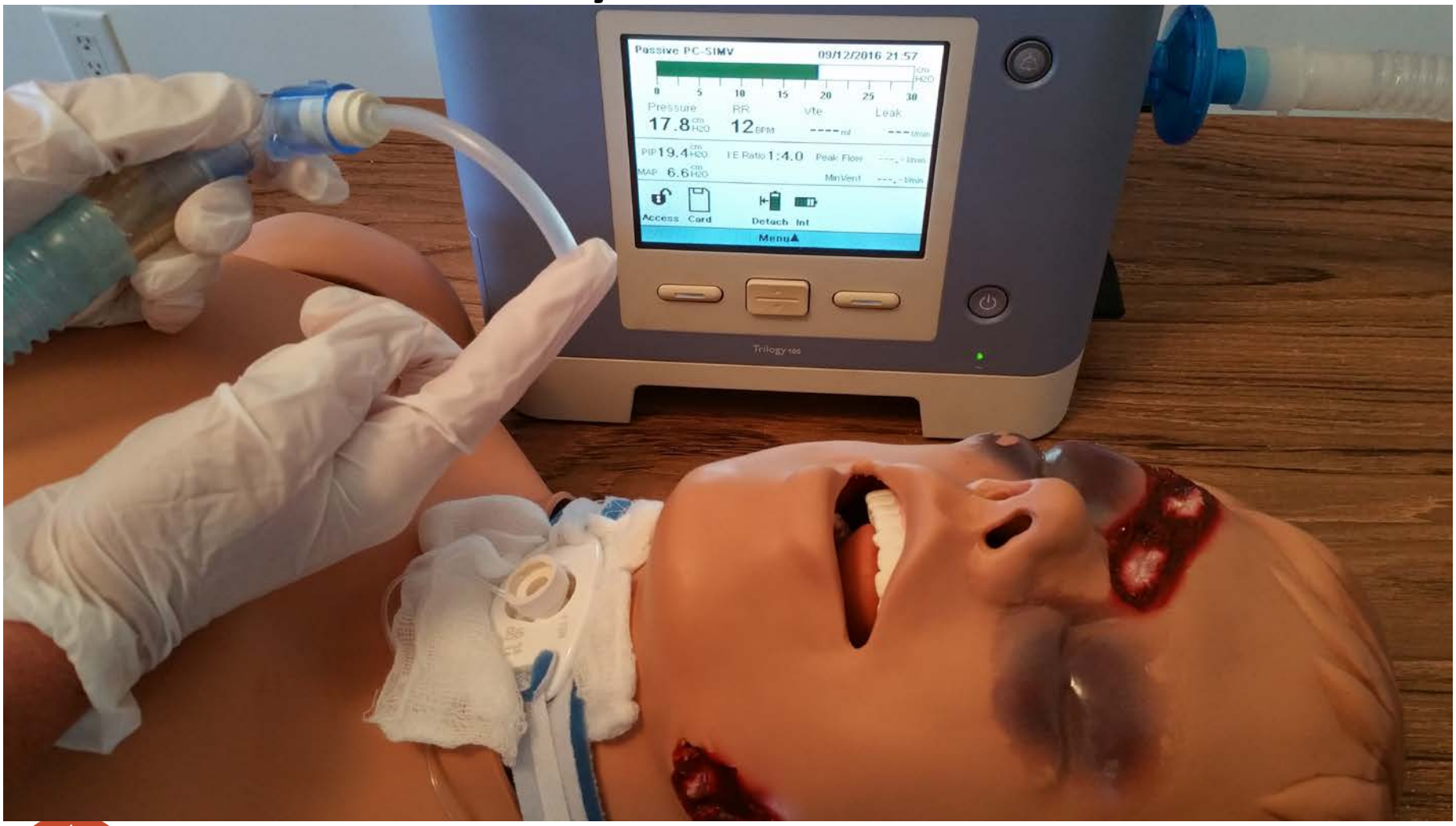
SIMV PC 20, PS 16, PEEP 4, 12 bpm



SIMV PC 20, PS 16, 12 bpm
Simulated Mucus Plug



Test By Obstruction



Pediatr Pulmonol. 2010 Mar;45(3):270-4.

How much do primary care givers know about tracheostomy and home ventilator emergency care?

Kun SS, Davidson-Ward SL, Hulse LM, Keens TG.

Division of Pediatric Pulmonology, Childrens Hospital Los Angeles, Keck School of Medicine of the University of Southern California, Los Angeles,

- 152 PC surveyed (108 parents, 44 nurses):

- 96% - expect a low pressure alarm with decannulation in Pressure Control
- 52% expect high pressure alarm with mucus plugging in Pressure Control

Causes of Death in Pediatric HMV

Table IV. Causes of death in 47 home mechanical ventilation patients by reason for chronic respiratory failure

Cause of death	Total n (%)	CPD n (%)	VMW n (%)	CHS n (%)	*P* value*
Progression of reason for CRF or other underlying condition	16 (34)	12 (26)	1 (2)	3 (6)	.13
Cardiac	10 (21)	6 (13)	3 (6)	1 (2)	.81
Acute respiratory failure	4 (8.5)	1 (2)	2 (4)	1 (2)	.68
Brain death	4 (8.5)	1 (2)	1 (2)	2 (4)	.68
Infectious/sepsis/MODS	4 (8.5)	1 (2)	1 (2)	2 (4)	.68
Tracheal bleeding	4 (8.5)	2 (4)	1 (2)	1 (2)	1
Tracheal obstruction	4 (8.5)	–	4 (8.5)	–	.01
Tracheostomy accident	1 (2)	–	–	1 (2)	.25
Total	47	23 (49)	13 (28)	11 (23)	

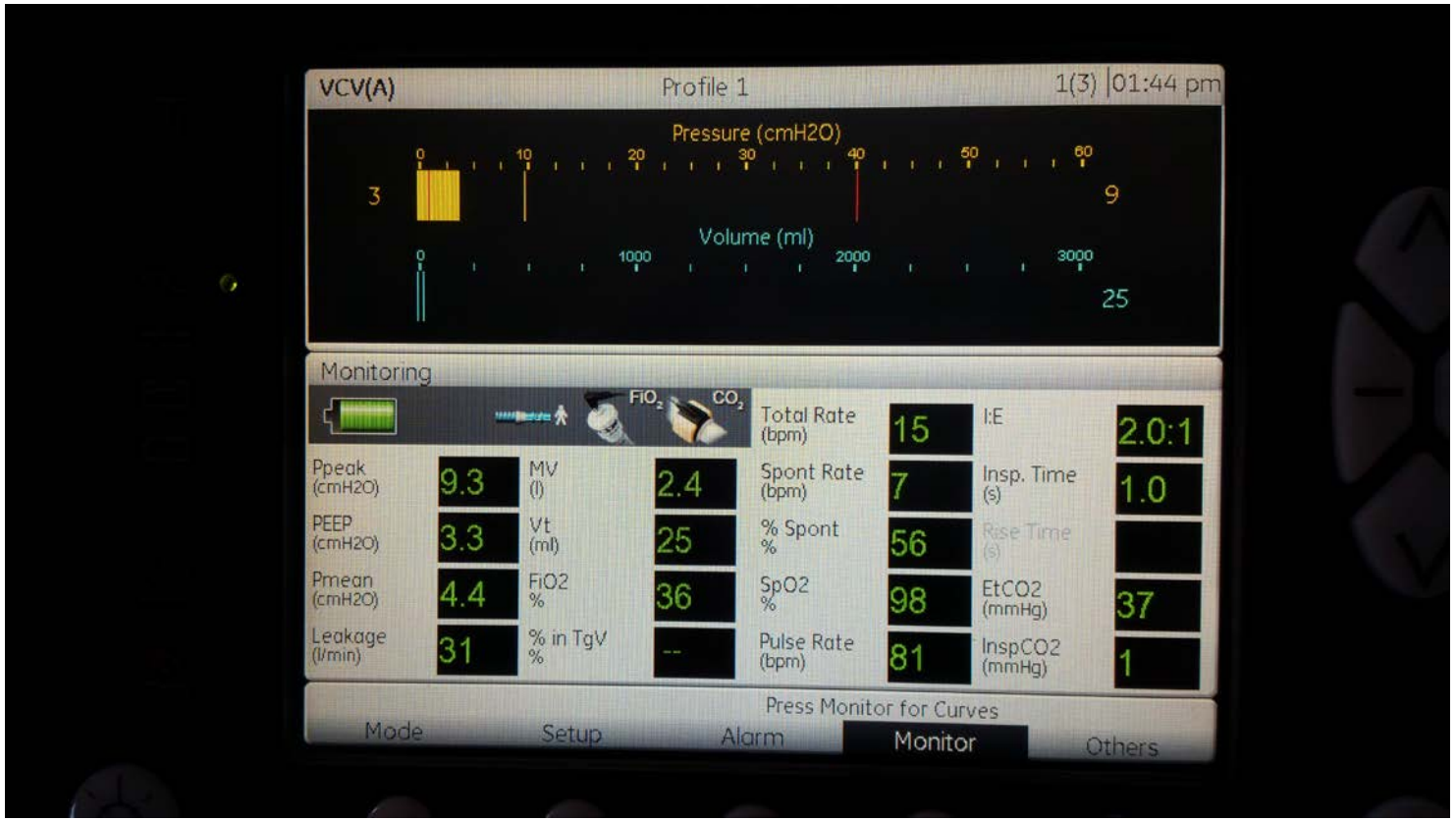
MODS, Multiple organ dysfunction syndrome.

Edwards, Journal of Pediatrics, 2010

FDA MAUDE DATABASE

Several deaths due to oxygen disconnection with no alarm (various home ventilators and CPAP, RADs).

Astral, HT 70, Vivo



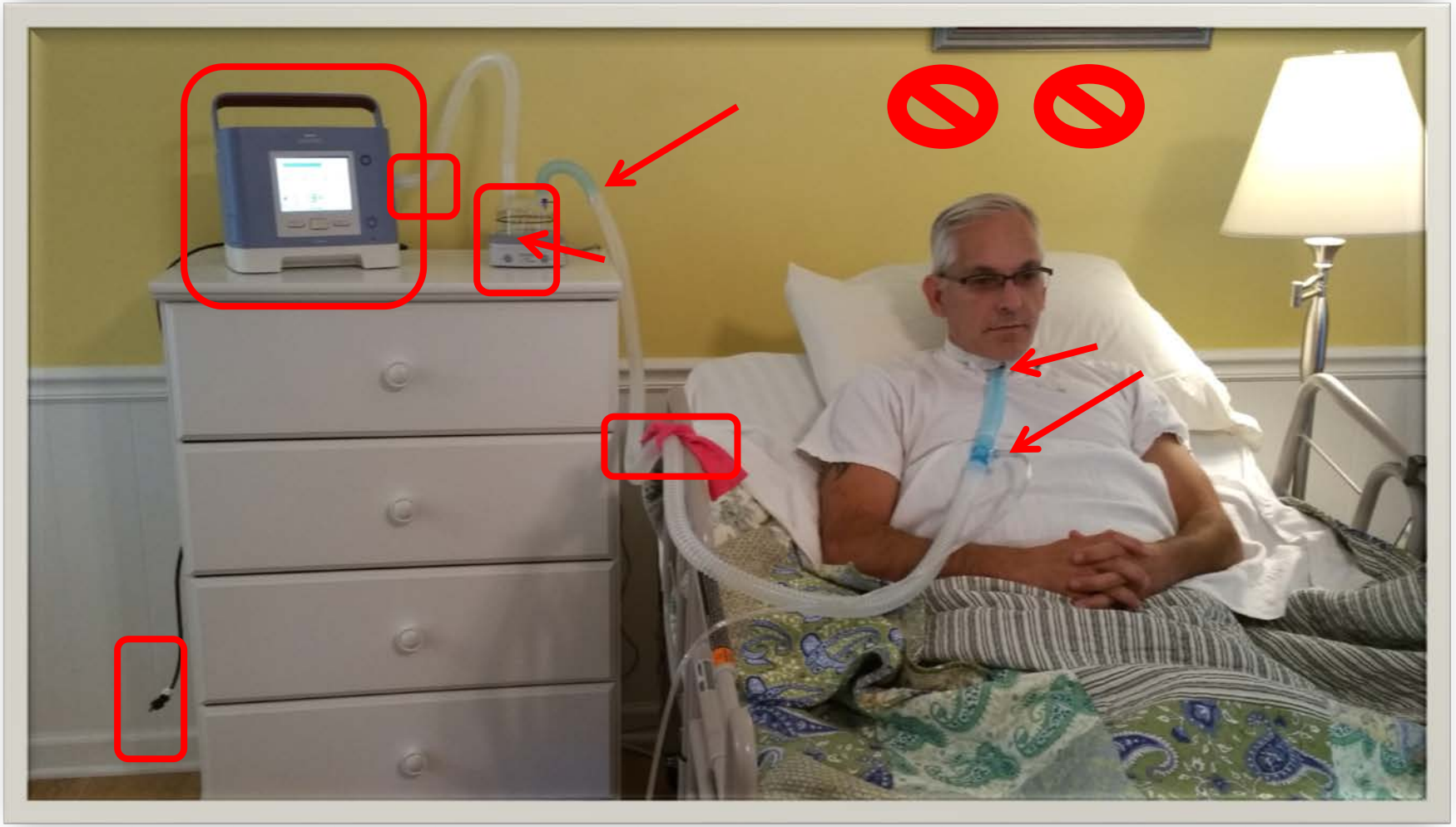
Steps RTs Can Take to Improve Patient Safety

CONGRESS 2016

How Many Safety Issues?

CONGRESS 2016

How Many Safety Issues?



CONGRESS 2016

Evaluate Emergency Plans

- Power Company
  - Priority restoration, pre-service interruption notification
- EMS / Fire
  - Home safety evaluation
  - Help with generator start-up
  - “Charge station” during power failure

Review Emergency Procedures With Family Periodically

It was reported that the pt passed away while connected to the ventilator. The pt had a mucus plug in the trach…. The family did not ambu bag with O_2 at the pt trach but **attempted to bag the pt by mouth via the mask.** The pt had a cuffed trach which was not deflated during bagging via mouth. The dealer stated the ventilator passed general testing.

Reassess Patient's Dependency Periodically

- Does patient need to move to a device with an internal battery?
  - Evaluate battery run time periodically
- Does patient need a resuscitation bag?
  - Remind to take with on all trips outside the home
  - Review proper use periodically
- Does patient need a "back-up" vent?

Make Sure the Alarms Can Be Heard Over Household Noise

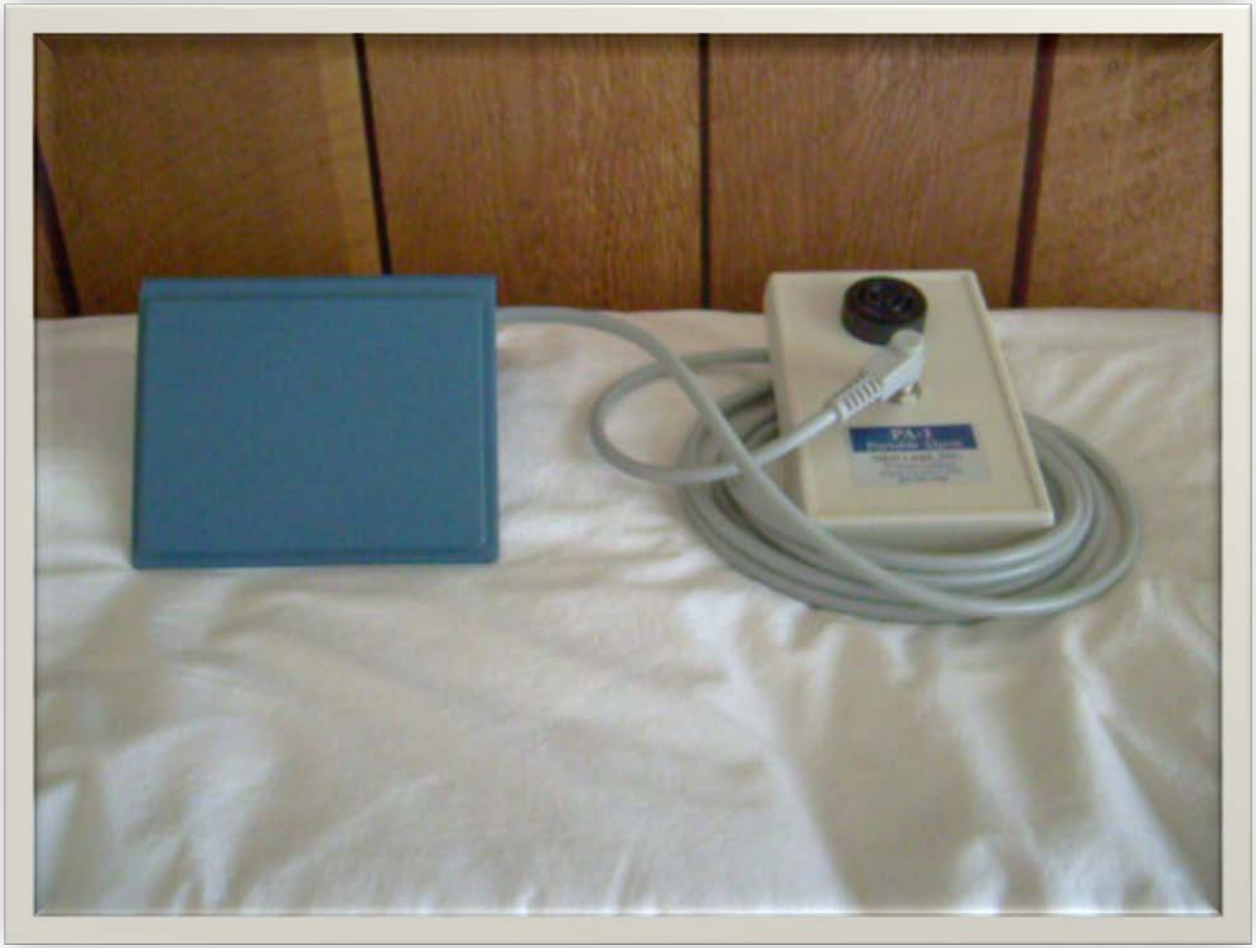
Liz Kowalczyk, Boston Globe, 12/11/2011

One day, when Liam was 3 years old, mucus blocked his breathing tube. Her husband was vacuuming…..By the time they discovered he was not getting enough air, Liam had suffered a brain injury that limits his ability to move.

Astral Remote Alarm

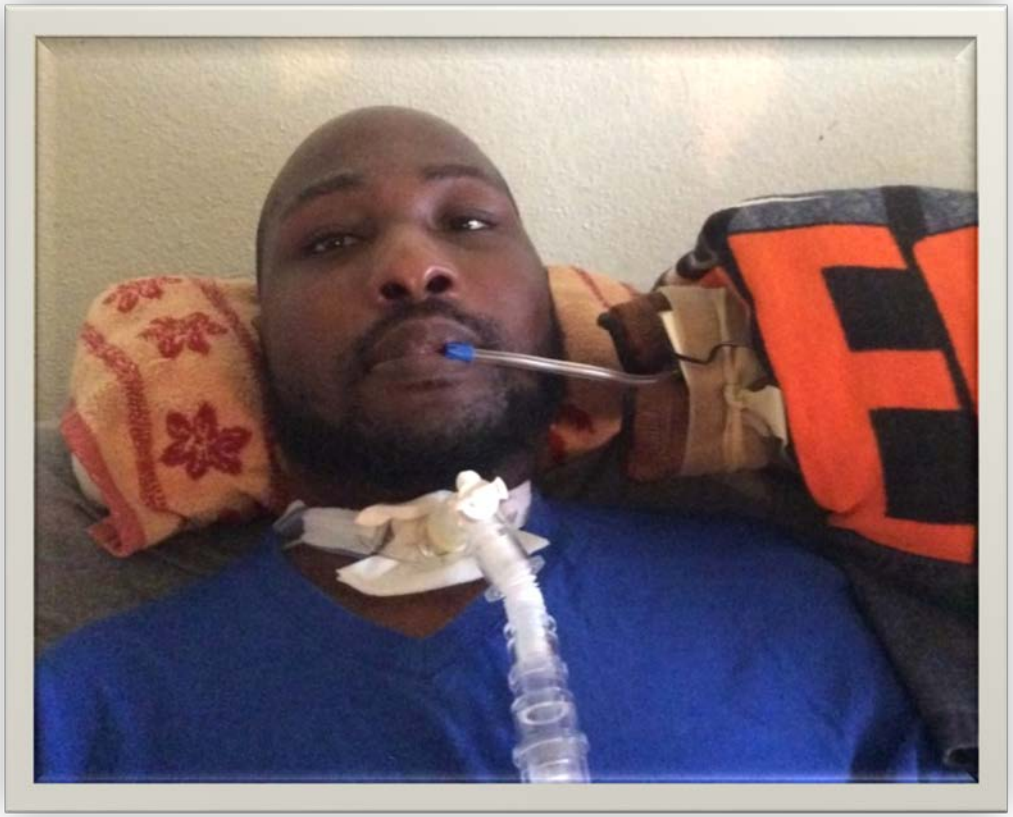
Light Blinker

Ensure that the Patient Can Call for Help



E-Z Call and PA-1 from Med Labs (Goleta, CA)

Ensure that the Patient Can Call For Help



Vent Moms Are More Likely to Be Tired & Depressed

Table 1. Demographic Variables for Caregivers*

Characteristic	Ventilator Dependent (n = 29)	Cystic Fibrosis (n = 42)	Healthy Comparison (n = 47)	$F_{2,115}$ Score	χ^2 Test
Age, y	37.9 ± 6.5	38.5 ± 6.1	38.4 ± 4.7	0.11	
Years of education	14.7 ± 1.9	15.1 ± 1.9	15.1 ± 1.9	0.47	
Married	24 (82.8)	37 (88.1)	45 (95.7)		3.53
Race					8.90†
White	25 (86.2)	42 (100)	46 (97.9)		
Black	4 (13.8)	0	1 (2.1)		
Employment					3.00
Full-time	10 (34.5)	14 (33.3)	15 (31.9)		
Part-time	8 (27.6)	9 (21.4)	19 (40.4)		
Not employed	11 (37.9)	19 (45.2)	13 (27.7)		
Psychotropic medications	7 (24.1)	7 (16.7)	11 (23.4)		0.80
Identified child's age	7.1 ± 3.1	7.3 ± 2.7	7.4 ± 2.7	0.13	
Other children in the home, No.					5.57
0	9 (31.0)	12 (28.6)	8 (17.0)		
1	9 (31.0)	21 (50.0)	23 (48.9)		
2	7 (24.1)	5 (11.9)	9 (19.1)		
≥3	4 (13.8)	4 (9.5)	7 (15.0)		
Age of other children in the home, y	8.5 ± 4.8	7.6 ± 4.2	7.8 ± 5.1	0.34	

*Unless otherwise indicated, data are reported as mean ± SD values or number (percentage) of subjects.

AARC CONGRESS 2016

Meltzer, Arch Int Med 2006

Table 2. Sleep-Wake Patterns and Daytime Functioning in Caregivers*

Characteristic	VENT	CF	HEALTHY	F Score	*P* Value
24-Hour SPI					
Bedtime†	22:55 ± 74 (20:00-1:27)	23:14 ± 63 (21:30-2:00)	23:11 ± 50 (21:21-1:21)	0.89	.41
Wake time†‡	6:21 ± 39 (5:03-7:30)	7:07 ± 68 (4:50-10:00)	7:01 ± 46 (5:57-10:00)	6.89	.001
Sleep onset latency, min	24.90 ± 18.7 (5.0-71.4)	17.74 ± 18.0 (0.5-90.0)	17.56 ± 12.9 (0.0-57.9)	2.16	.12
Night waking frequency§	1.39 ± 0.9 (0-3.6)	1.12 ± 0.9 (0-3.5)	0.85 ± 0.7 (0-3.1)	3.43	.04
TST, h‡	6.31 ± 1.2 (3.3-8.4)	7.28 ± 0.9 (5.0-9.8)	7.34 ± 0.9 (5.2-9.8)	11.05	<.001
Sleep quality (1-5 scale)§	3.33 ± 0.7 (1.9-5.0)	3.73 ± 0.7 (2.5-5.0)	3.82 ± 0.7 (1.9-4.9)	4.19	.02
PSQI¶					
Sleep quality‡	1.45 ± 0.7 (0-3)	1.29 ± 0.6 (0-3)	1.00 ± 0.7 (0-3)	4.08	.02
Sleep latency‡	1.52 ± 0.9 (0-3)	1.05 ± 0.7 (0-3)	0.89 ± 0.9 (0-3)	5.75	.004
Sleep duration‡	2.28 ± 0.8 (1-3)	1.45 ± 1.0 (0-3)	1.32 ± 0.9 (0-3)	11.12	<.001
Sleep efficiency§‖	1.17 ± 1.2 (0-3)	0.71 ± 0.9 (0-3)	0.23 ± 0.6 (0-3)	10.22	<.001
Sleep disturbances	1.31 ± 0.7 (0-3)	1.14 ± 0.4 (1-2)	1.15 ± 0.5 (0-2)	1.16	.32
Sleep medications	0.62 ± 1.0 (0-3)	0.60 ± 1.1 (0-3)	0.34 ± 0.7 (0-3)	1.18	.31
Daytime functioning‡	1.72 ± 0.9 (0-3)	1.12 ± 0.8 (0-3)	1.00 ± 0.9 (0-3)	6.57	.002
Global score‡	10.07 ± 3.7 (2-18)	7.36 ± 3.6 (2-17)	5.94 ± 3.2 (1-15)	12.98	<.001
Depression§¶	15.10 ± 9.5 (1-36)	10.83 ± 8.9 (0-36)	9.28 ± 8.5 (0-35)	3.92	.02
Fatigue§¶	31.34 ± 5.2 (20-38)	28.40 ± 6.1 (17-46)	26.40 ± 7.1 (12-43)	5.50	.005

Abbreviations: CF, mothers of children with cystic fibrosis; HEALTHY, mothers of healthy children; PSQI, Pittsburgh Sleep Quality Index[37]; SPI, Sleep Patterns Inventory; TST, total sleep time; VENT, mothers of children with ventilator dependency.

*Unless otherwise indicated, data are reported as mean ± SD (range).

†Bedtimes and wake times are expressed as times on the 24-hour clock; standard deviations are expressed in number of minutes.

‡Significant difference between VENT and both CF and HEALTHY.

§Significant difference between VENT and HEALTHY.

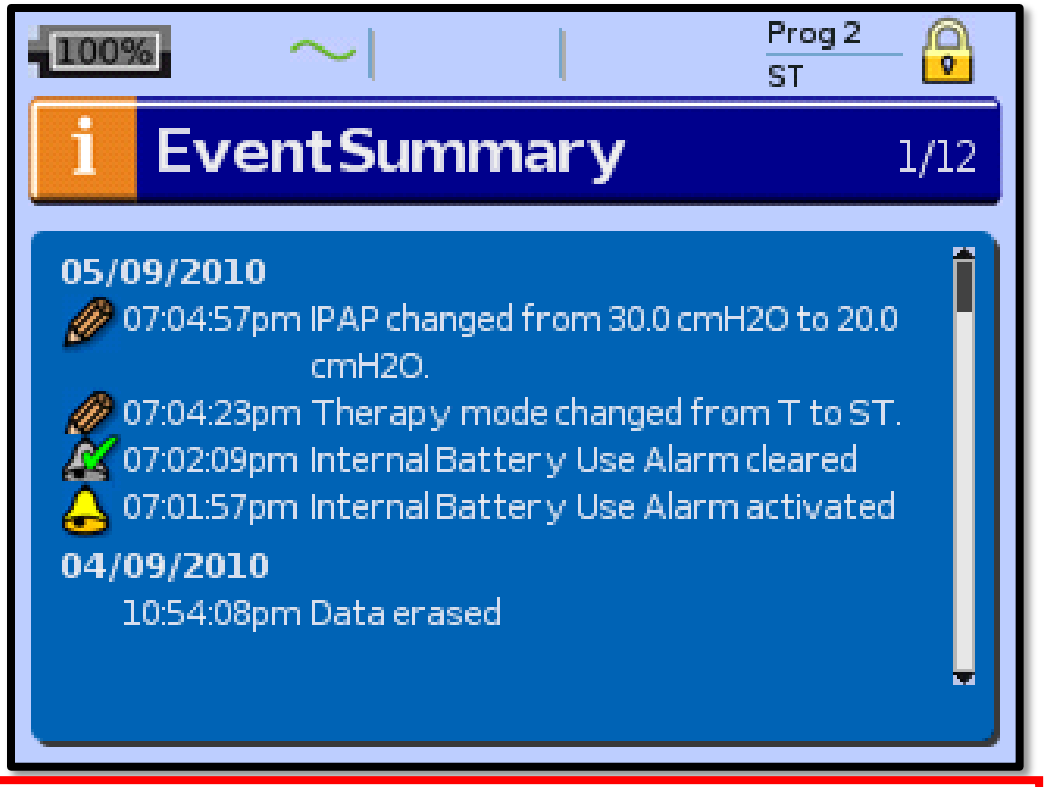
‖Significant difference between CF and HEALTHY.

¶Higher scores indicate more negative functioning.

Screen for Alarm Fatigue

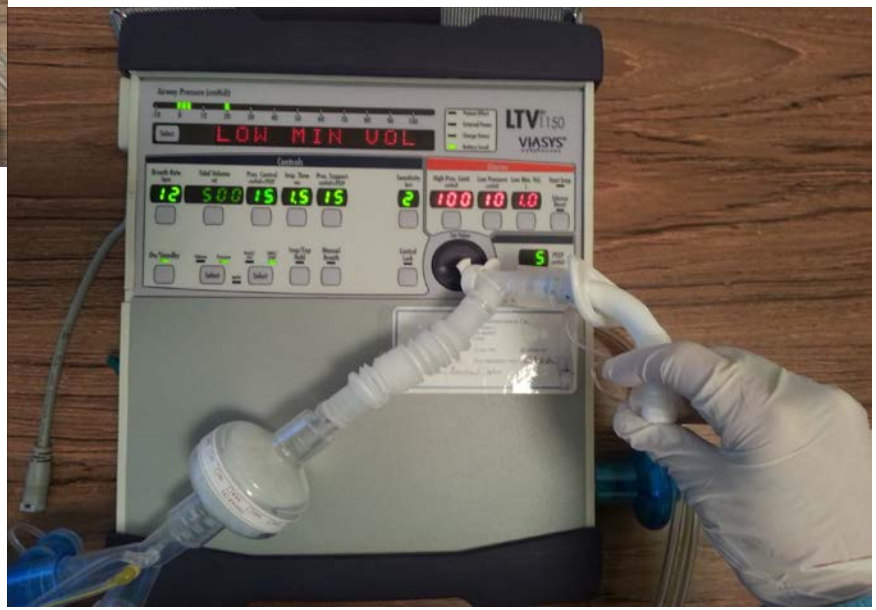
"Nurses and other caregivers can become desensitized to audible warnings when they hear beeps all day long, many of them false alarms".

Liz Kowalczyk, Boston Globe, 12/11/2011



Minimize nuisance alarms when possible with delay or duration features!

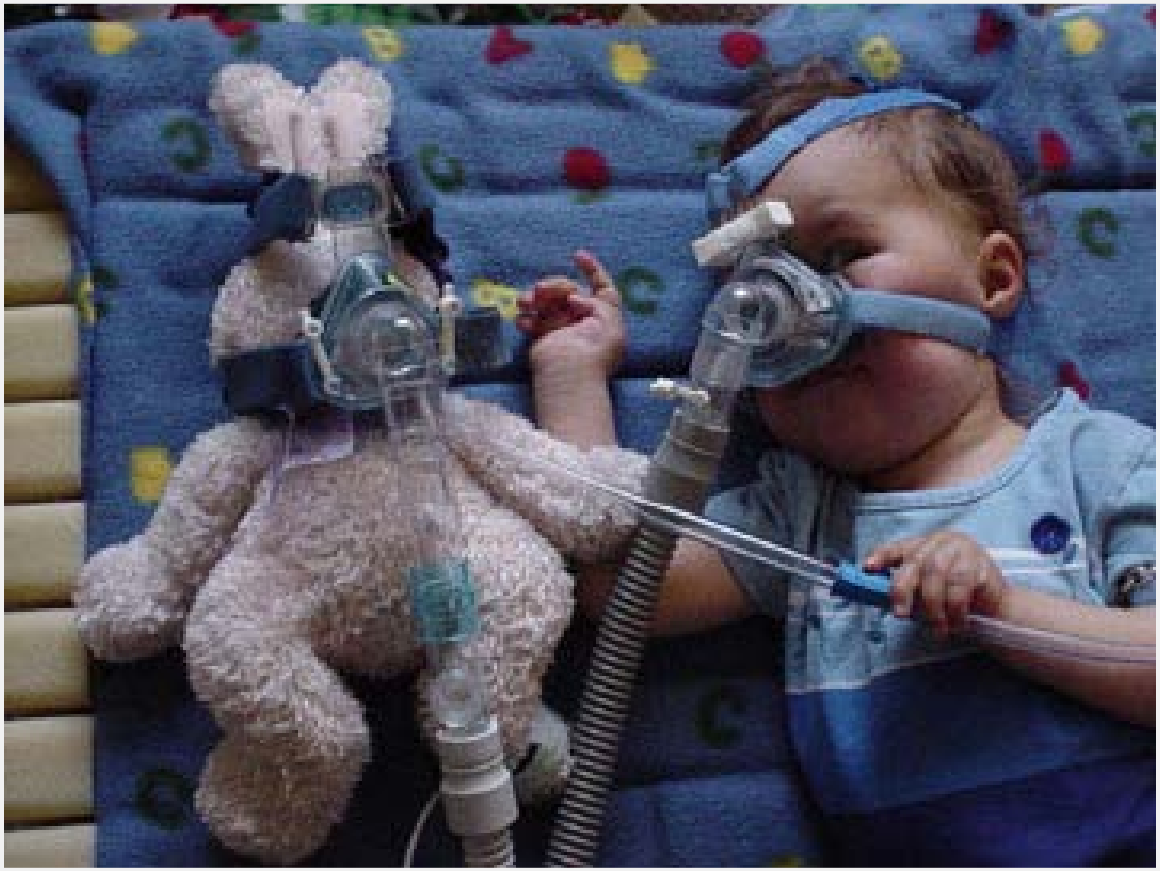
Check Alarms With Emergency Trach Tube!



Summary

- Reassess patient's dependency periodically.
- Consider outcome of O_2 disconnection.
- Simulate decannulation and obstruction.
- Unplug the vent from AC power and ensure that it alarms and switches to battery power.
  - Test battery duration periodically.
- Verify alarms can be heard.
- Verify ambu-bag handy and family trained.
- Verify spare trach tube handy and family trained in handling trach emergencies.

Questions? Comments?



angela.king@
mobilemedicalhomecare.org

CONGRESS 2016

Survival on HMV

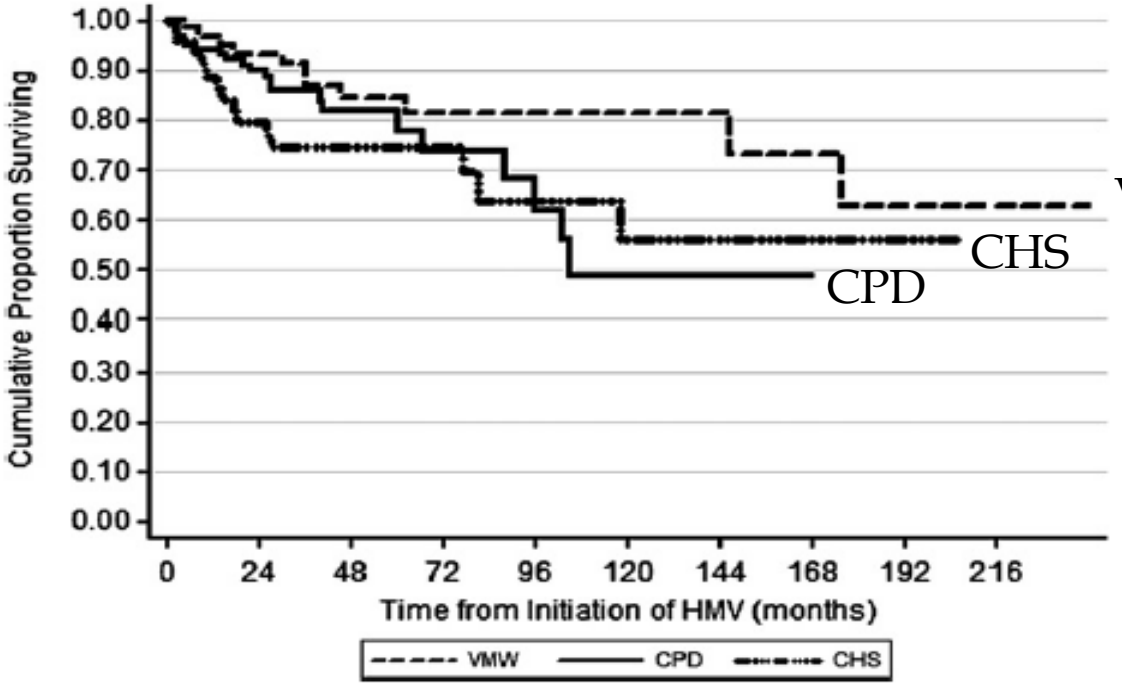


Figure 2. Kaplan-Meier survival curves for 228 children on HMV by reason for CRF.

Edwards, Journal of Pediatrics, 2010

VAMP

- Discuss number of vents and 27% of deaths accidental.
- Discuss nurse education issues